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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,289	08/15/2000	Mahendra G. Dedhiya	10/042	1566

7590

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/639,289

Applicant(s)

DEDHIYA ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-12 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 7-12, and 14-23 are pending. The Amendment filed 12/9/02, Paper No. 21, cancelled claim 13, and amended claims 1, 3-4, 7-8, 10 and 12.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 12/9/02 (Paper No. 21) to the rejection of claims 1-4 and 7-22 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's amendments and arguments filed 12/9/02 (Paper No. 21) are persuasive to overcome the 35 USC 112 rejections in the previous Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-12, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (5,716,638) in view of Patel et al. (6,294,192) in further view of LaMastro et al. (5,258,336).

Touitou teaches medical compositions for topical application to the skin. Disclosed is a composition comprising 7uci/ml tetrahydrocannabinol, 49% ethanol, 19.6% propylene glycol, and 29.4% water. It is further disclosed that ethanol can comprise 15-30% of the composition, propylene glycol can comprise up to 20% of the composition, and water can comprise at least 20% of the composition. The composition particles are disclosed as having a size ranging from

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.01-8.2 um. See Col. 1, line 11-Col. 3, line 25. The reference fails to teach aerosolization, preferred ratios and dosages, and containers.

Patel et al. teach triglyceride-free pharmaceutical compositions for delivery of hydrophobic therapeutic agents. Disclosed are composition comprising a hydrophobic therapeutic agent and a carrier, wherein the carrier is formed from a combination of a hydrophilic surfactant and a hydrophobic surfactant. The hydrophobic therapeutic agent is disclosed as comprising 0.1-60% by weight of the composition. Tetrahydrocannabinol is disclosed as a therapeutic agent. Ethanol and propylene glycol are disclosed as preferred solubilizers that can be combined in composition. The solubilizer is disclosed as comprising 1-100% of the composition. Dosage forms wherein the composition is dispersed with water are disclosed. The composition can take on the form of a spray or an aerosol for pulmonary administration. Human administration is disclosed as preferable. See Col. 4, line 50-Col. 5, line 8; Col. 21, lines 47-line 67; Col. 24, line 59-Col. Col. 26, line 60; Col. 28, lines 14-40; Col. 30, lines 25-35; Col. 31, lines 1-35.

LaMastro et al. teach low expansion type 1 amber glass containers. These containers are disclosed for holding pharmaceutical preparations that require packaging that provides a high degree of chemical stability and protection from ultraviolet light. See Col. 1, lines 10-19 and lines 62-68.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Touitou in the form of an aerosol, as taught by Patel et al. because a) Patel et al. and Touitou both teach compositions comprising THC, ethanol, propylene glycol, and water; b) Patel et al. teach topical, transdermal, and aerosol forms of the composition

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as possible and interchangeable, and Touitou teach topical, and transdermal forms of his composition; hence, the replacement of one pharmaceutical form (topical) of the composition for the other (aerosol) for pharmaceutical purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of the combined references in the type 1 amber glass container of LaMastro et al. because a) the combined references teach a composition in the form aerosol, and a composition that results in aerosolization must be housed in a closed container; thus since LaMastro et al. teach their containers for pharmaceutical use and as providing a high degree of chemical stability and protection from ultraviolet light, teaching the container of the combined references as a type 1 amber container would be within the skill of one of in the art.

Response to 103 Arguments

Applicant argues, "Applicants use functional language to limit the composition to one suitable for delivery to the lungs so as to allow transfer of the delta-9-tetrahydrocannabinol into the bloodstream. Such a composition is distinct from the topical forms taught by Touitou and the oral forms taught by Patel et al. Functional language in a claim for a composition is a proper limitation". While the Examiner agrees that functional language in a claim can be a proper limitation, this argument is not persuasive. The Examiner respectfully points out that since Touitou teaches a composition comprising the same constituents and amounts, and particle size of that of the instant invention, then his compositions must have the property of having a mean mass median aerodynamic diameter in the range from about 1 to 10 micrometers. Additionally, regarding functional language, the Examiner respectfully reminds Applicant that functional language at the point of novelty is not proper. Attention is directed to *General Electric Company*

v. Wabash Appliance Corporation et al 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Claims employing functional language at the point of novelty neither provide those elements required to practice the inventions, nor "inform the public during the life of patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et supra*, at 468.

Applicant argues, "However, Patel et al. do not teach a pharmaceutical composition suitable for rapid delivery to a lung of a subject and subsequently to the bloodstream; nor does it teach a stable clear solution near the solubility point of delta-9-tetrahydrocannabinol such that the partitioning is enhanced". This argument is not persuasive. It is respectfully pointed out that Patel et al. is merely relied upon as a secondary reference to teach the interchangeability of topical and aerosol forms of pharmaceutical compositions

Applicant argues, "Further, Patel et al. do not teach or disclose how to formulate an aerosolized composition suitable for rapid delivery to a lung of a subject". This argument is not persuasive, as the recitation "suitable for rapid delivery to a lung of a subject" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended

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use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues, “The single reference to an aerosolized composition is for a composition suitable for coating beads for oral delivery”. This argument is not persuasive, as it is not accurate. The Examiner respectfully points out that in Col. 26 of Patel et al., it teaches, “The compositions of the present invention can also be formulated as a spray or an aerosol. In particular, the compositions may be formulated as a sprayable solution, and such formulation is particularly useful for spraying to coat a multiparticulate carrier, such as a bead”. Thus, the reference does not limit aerosolized compositions to those suitable for coating beads. The Examiner respectfully points out that Patel et al. is directed toward compositions comprising hydrophobic active ingredients, wherein THC is a hydrophobic active ingredient taught by Patel et al. Patel et al. teach the interchangeability of topical, transdermal, and aerosol compositions of hydrophobic active ingredients. Thus, Patel et al. was relied upon to teach the interchangeability of composition forms.

Applicant argues, “Finally, Patel et al. suggest the mixing of the pharmaceutical composition with water just before administration”. This argument is not persuasive. The Examiner respectfully points out Patel et al. is relied upon merely to teach the interchangeability of composition forms. Touitou is the primary reference which teaches the composition.

Conclusion

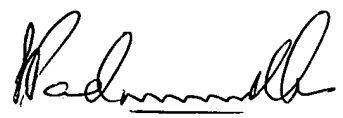
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


SREENI PADMANABHAN
PRIMARY EXAMINER 1/25/03